



Attorney Docket No. 102258.170US2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

LOSCALZO et al.

Serial No.:

10/687,706

Examiner: To Be Assigned

Filed:

October 20, 2003

Group Art Unit: 1651

For:

METHODS OF TREATING VASCULAR DISEASES CHARACTERIZED

BY NITRIC OXIDE INSUFFICIENCY

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants and their legal representatives hereby make of record on the attached Form PTO-1449 the following publications which are known to them and considered warranting disclosure under 37 C.F.R. §1.56 and 1.97-98. Copies of any cited patents and/or U.S. patent publications are not being submitted in accordance with 37 C.F.R. §1.98(a)(2)(1). However, copies of the cited articles are enclosed.

It is respectfully requested that the information above be expressly considered during the prosecution of this application and that the publications be made of record therein and appear among the "References Cited" on any patent to issue therefrom. In this regard, it is requested that the Examiner initial and return a copy of the enclosed Form PTO-1449 with the next Patent Office Communication.

The submission of the publications does not constitute a representation by the Applicants that a search has been made or that no better art exists and does not constitute an admission that the listed publications are material or constitute "prior art." Applicants reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed publications, should one or more of the publications be applied against the claims of the present application.

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It is Applicants' belief that the filing of this Information Disclosure Statement precedes the date of the mailing of the first Office Action on its merits, therefore, pursuant to 37 C.F.R. §1.97(b)(3), no fee is believed to be due.

In the event a fee is due, the Commissioner is authorized to charge any fee deficiency or credit any overpayment to Deposit Account No. <u>08-0219</u>.

Dated: November 15, 2004

Respectfully submitted,

Edward D. Grieff

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Attorney for Applicants

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PTO/SB/08a (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

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Substitute for form 1449A/PTO

Complete if Known Application Number 10/687,706 Filing Date 10/20/2003 First Named Inventor... LOSCALZO, et al. Art Unit 1651 **Examiner Name** To Be Assigned

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Attorney Docket Number 102258.170US2 3

				U. S. PATENT D		
Examiner nitials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (ft known)}		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
			5,760,069	06/02/1998	Lukas-Laskey et al.	
			5,902,821	05/11/1999	Lukas-Laskey et al.	
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	FOREIGN PATENT DOCUMENTS									
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶				

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Substitute for form 1449B/PTO		Complete if Known
	Application Number	10/687,706
INFORMATION DISCLOSURE	Filing Date	10/20/2003
STATEMENT BY APPLICANT	First Named Inventor	LOSCALZO, et al.
	Art Unit	1651
(Use as many sheets as necessary)	Examiner Name	To Be Assigned
Sheet 2 of 3	Attorney Docket Number	102258.170US2

		NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					
	AA	FRANCIOSA, Joseph A., "African-American Heart Failure Trial (A-HeFT): Rationale, Design, and Methodology," Journal of Cardiac Failure, Vol. 8, No. 3, 2002, pp. 128-135					
	АВ	YANCY, Clyde W., et al., "Race and the Response to Adrenergic Blockage with Carvedilol in Patients with Chronic Heart Failure," N. Engl. J. Med., Vol. 344, No. 18, May 3, 2001, pp. 1358-1365					
	AC	YANCY, Clyde W., "Heart Failure in African Americans: A Cardiovascular Enigma," Journal of Cardiac Failure, Vol. 6, No. 3, 2000, pp. 183-186					
	ΑD	EXNER, Derek V., et al., "Lesser Response to Angiotensin-Converting-Enzyme Inhibitor Therapy in Black as Compared with White Patients with Left Ventricular Dysfunction," N. Engl. J. Med., Vol. 344, No. 18, May 3, 2001, pp. 1351-1357					
	AE	PACKER, Milton, et al., "Effect of Carvedilol on Survival in Severe Chronic Heart Failure," N. Engl. J. Med., Vol. 344, No. 22, May 31, 2001, pp. 1651-1658					
***************************************	AF	"A Trial of the Beta-Blocker Bucindolol in Patients with Advanced Chronic Heart Failure," N. Engl. J. Med., Vol. 344, No. 22, May 31, 2001, pp. 1659-1667					
	AG	BRAUNWALD, Eugene, "Expanding Indications for Beta-Blockers in Heart Failure," N. Engl. J. Med., Vol. 344, No. 22, May 31, 2001, pp. 1711-1712					
••••••	АН	SCHWARTZ, Robert S., "Racial Profiling in Medical Research," N. Engl. J. Med., Vol. 344, No. 18, May 3, 2001, pp. 1392-1393					
	Al	LEVINE, T. Barry, "Paradoxical Hypertension after Reversal of Heart Failure in Patients Treated with Intensive Vasodilator Therapy," American Journal of Hypertension, Ltd., 1998; 11:1041-1047					
	AJ	ABSTRACTS - Heart Failure 179A, JACC, February 1999					

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Sheet 3	Attorney Docket Number	102258.170US2

	NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*								
	AK	KAHN, Jonathan, "How a Drug Becomes "Ethnic": Law, Commerce, and the Production of Racial Categories in Medicine," Yale Journal of Heath Policy, Law, and Ethics IV:1 (2004), pp. 1-46						
	AL	PARKER, John D., et al., "The Effect of Hydralazine on the Development of Tolerance to Continuous Nitroglycerin," The Journal of Pharmacology and Experimental Therapeutics, Vol. 280, No. 2, pp. 866-875						
	АМ	KALINOWSKI, Leszek, et al., "Race-Specific Differences in Endothelial Function - Predisposition of African Americans to Vascular Diseases," Circulation, June 1, 2004, pp. 2511-2517						

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